

U.S. Patent Application No. 10/019,995  
Amendment dated December 27, 2004  
Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

**REMARKS/ARGUMENTS**

Reconsideration and continued examination of the above-identified application are respectfully requested.

The applicants would like to thank Examiner Kam for the courtesy of a telephone interview on December 14, 2004. During the interview, the claim amendments presented herein were discussed (the Examiner was provided in advance with an unofficial copy of the Amendment) and the Examiner stated that she believed that the claim amendments would overcome the outstanding rejections in the application. The Examiner requested that the specification be amended to include the term "endosperm" during the discussion relating to the removal of albumen, since the term endosperm is what is used in the claims. The Examiner acknowledged that persons skilled in the art would recognize that "endosperm" and "albumen" can be used interchangeably. Accordingly, this amendment does not constitute new matter. The Examiner further requested that the withdrawn claims, claims 12, 14, 22 and 30 be canceled. These claims are non-elected claims that were withdrawn from consideration following a restriction requirement in the Office Action of January 15, 2004, which restriction was made final in the Office Action of July 26, 2004. Applicants reserve the right to file a divisional application directed to the subject matter of the canceled claims.

The amendment to the claims is editorial in nature and/or further defines what applicants regard as their invention. In addition to the amendments discussed herein with respect to specific rejections, claim 6 is amended to correct a spelling error. Full support for the amendments can be found throughout the present application, including the claims as originally filed. The amendments presented herein are limited to those that place the claims into better form for allowance or appeal. In particular, the amendments provide further clarification of subject matter

U.S. Patent Application No. 10/019,995  
Amendment dated December 27, 2004  
Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

that was already contained and examined in the claims and do not present new issues for consideration. Accordingly, the applicants respectfully request that the amendments be entered under 37 CFR §1.116. Accordingly, no questions of new matter should arise, and entry of the amendment is respectfully requested.

Claims 1 - 11, 13, 15 - 21, and 23 - 29 are pending in the application and claims 12, 14, 22, and 30 have been canceled.

**Rejection of Claims 1 - 11, 15 - 21, and 23 - 29 under 35 U.S.C. §112, second paragraph**

At page 4 of the Office Action, claims 1 - 11, 15 - 21, and 23 - 29 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention.

Regarding claim 1, the Examiner alleges that there is insufficient basis for the limitation "the systems" in line 3. The Examiner further alleges that claims 1 - 11, 15 - 21 and 23 - 28 are indefinite as to the term "an endosperm portion." The Examiner alleges that it is unclear as to whether the whole endosperm or a portion of the endosperm of the cell extract is excluded. Claims 2 - 11, 15 - 21, and 23 - 28 were included in this rejection as being dependent on claim 1.

For the following reasons, these rejections are respectfully traversed. In particular, it is respectfully submitted that the use of the phrase "substantially excluding an endosperm portion" is a grammatically correct way of indicating that the entire endosperm is excluded. Clearly, in plain English, the word "portion" serves not to indicate that the endosperm is divided into portions, but to differentiate the endosperm from other, non-endosperm portions of the cell extract. This interpretation is supported by the discussion on pages 9 - 11 of the present application wherein it is discussed that germ extracts for cell-free protein synthesis are prepared

U.S. Patent Application No. 10/019,995  
Amendment dated December 27, 2004  
Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

by completely excluding albumen (synonymous with endosperm) from the extracts. Moreover, the recitation of "the systems" does not lack antecedent basis, since the present specification clearly teaches that cell extracts, as described therein, inherently contain systems that are involved in inhibiting protein synthesis. Without conceding the correctness of the rejection and to further clarify the invention, claim 1 is amended to specify that the cell extract is prepared by substantially excluding all endosperm of the cell extract. Further, claim 1 is amended to remove "the" from before the term "systems," thereby removing the necessity to provide antecedent basis for the term.

Regarding claim 4, the Examiner alleges that there is insufficient basis for the limitation "the inhibiting of said systems" since claim 1 only indicates that the systems involved in inhibiting the protein synthesis of the cell extract are excluded, not inhibited. Claims 19 and 26 are included in this rejection. For the following reasons, this rejection is respectfully traversed.

In response, claim 4 is amended to recite "the excluding of said systems" instead of "the inhibiting of said systems." It is respectfully submitted that this amendment is a correction of an obvious error.

Regarding claim 5, the Examiner alleges that the phrase "a substance is present which controls deadenylation of ribosomes" is indefinite on the alleged grounds that it is unclear whether the substance is from the cell extract or is added to the cell extract. Claims 20 and 27 are included in this rejection. For the following reasons, this rejection is respectfully traversed.

Claim 1 is directed to a preparation "comprising" a cell extract. The use of the term "comprising" indicates that the preparation can include other ingredients. Claim 5 indicates that the substance that controls deadenylation of ribosomes is "present" in the preparation. It is respectfully submitted that it is not necessary for the sake of clarity to specify whether the

U.S. Patent Application No. 10/019,995

Amendment dated December 27, 2004

Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

substance is from the cell extract or is added to the cell extract. The claim clearly covers either alternative.

Regarding claims 10 - 11 and 23 - 29, the Examiner alleges that the claims are indefinite because they lack essential steps in the method for cell-free protein synthesis. The Examiner alleges that the omitted steps are the addition of indispensable substances used for in vitro protein synthesis and a step regarding how the protein synthesis is carried out using the cell extract and the indispensable compounds. For the following reasons, this rejection is respectfully traversed.

Claims 10 - 11 are directed to methods of protein synthesis using the preparation of claim 1 and further providing that a carrier or a dialysis membrane, respectively, is used in the method. Claims 23 - 29 are directed to methods of protein synthesis using the preparations of claims 1 - 6 and 13, respectively. It is respectfully submitted that the claimed methods would be clear and definite to persons skilled in the art. Without conceding the correctness of the rejection, claims 10 - 11 and 23 - 29 are amended to provide even greater grammatical clarity and to explicitly set forth method steps for carrying out cell-free synthesis. The Examiner's allegation that the claims omit a step of adding indispensable compounds to the cell extract is overcome in the amended claims by reciting a step of providing raw material substances that participate in cell-free synthesis. This recitation is supported in the present specification on page 12, line 21, through page 13, line 20, for example. Further, the amended claims explicitly contain a step of carrying out protein synthesis to obtain a protein product. Still further, claim 10 is amended to clarify the role that the carrier capable of molecular sieving plays in the synthesis process by clarifying that the product protein is separated from other materials by differences in the movement of the product material and other materials through the carrier. Claim 11 is amended to clarify the role

U.S. Patent Application No. 10/019,995

Amendment dated December 27, 2004

Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

that the dialysis membrane plays in the synthesis process by clarifying that the reaction vessel is separated by the dialysis membrane into a reaction phase and an external phase and that the product protein is separated into the external phase through the dialysis membrane. Still further, claims 10 and 11 are amended to include a step of recovering the separated synthesized protein.

In view of the above discussion, it is respectfully submitted that all of the rejections of claims 1 - 11, 15 - 21 and 23 - 29 under 35 U.S.C. §112, second paragraph, are overcome. Withdrawal of the all of the rejections of claims 1 - 11, 15 - 21 and 23 - 29 under 35 U.S.C. §112, second paragraph, is respectfully requested.

**Rejection of Claims 1, 4, 5, 23, 26, and 27 under 35 U.S.C. §102 over Endou**

Claims 1, 4, 5, 23, 26, and 27 were rejected under 35 U.S.C. § 102(b) as being anticipated by Endou (JP-07203984). The Examiner alleges that Endou teaches a ribosome inactivation protein, named Torichin (tritin), that is found in wheat germ and that can inactivate ribosomes by removing an adenine from 28S rRNA. The Examiner further alleges that a wheat germ extract is prepared by removing Torichin activity by affinity column separation using a Torichin antibody. The Examiner further alleges that the efficiency of protein synthesis in a wheat germ cell-free protein synthesis system is increased by using the Torichin antibody and removing the neutralized Torichin protein. The Examiner further alleges that claim 1 only indicates that "an endosperm portion" of a cell extract is excluded and does not specify what endosperm and what method is used to remove the endosperm portion. The Examiner takes the position that the removal of the Torichin protein with a Torichin antibody constitutes the removal of "an endosperm portion," and therefore, the Examiner takes the position that the use of the germ extract in protein synthesis meets the limitations of claim 1.

U.S. Patent Application No. 10/019,995  
Amendment dated December 27, 2004  
Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

For the following reasons, this rejection is respectfully traversed. As discussed above, independent claim 1 relates to a method of cell-free protein synthesis using a cell extract prepared by excluding all endosperm of the cell extract. As explained above, and as further clarified by the amendment to claim 1, the method covers a preparation where the cell extract is prepared by substantially excluding all endosperm from the extract.

Further to the clarification of the limitations of claim 1 discussed above, the arguments set forth in Applicants' response of April 15, 2004 are incorporated herein. In particular, it is respectfully submitted that Endou only discloses a wheat germ extract prepared by removing one substance, Torochin (tritin), from the extract. Since the method used to remove the Torochin is affinity column separation using an anti-Torochin antibody, only Torochin is removed in the method of Endou. Endou does not teach or suggest a preparation prepared by removing all of the endosperm from a cell extract. Exclusion of inhibitory substances other than tritin contained in the endosperm cannot be accomplished by the method described in Endou. These other substances have a substantial affect on protein synthesis and according to the present invention, are removed by excluding the endosperm from the cell free abstract according to the preparation and methods of the present invention.

Accordingly, claims 1, 4, 5, 23, 26, and 27 are not anticipated by, and would not have been obvious over, Endou. Withdrawal of the rejection under 35 U.S.C. § 102 over Endou is therefore respectfully requested.

### CONCLUSION

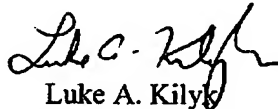
In view of the foregoing remarks, the Applicants respectfully request the entry of the above amendments, reconsideration of this application in view of the amendments and

U.S. Patent Application No. 10/019,995  
Amendment dated December 27, 2004  
Reply to Office Action of July 26, 2004 and Advisory Action of October 28, 2004

arguments made herein and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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